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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,937

10/13/2004

Hubert Thoma

H-32407A

6977

74479 7590 01/27/2010

Novartis Animal Health US Inc.  
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Greensboro, NC 27408

EXAMINER

LEVY, NEIL S

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

01/27/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/506,937	<b>Applicant(s)</b> THOMA ET AL.	
	<b>Examiner</b> NEIL LEVY	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 5/19/09.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-26,32-34,37-40,42-46,& 48-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-26,32-34,37-40,42-46,& 48-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 24, 26, 32-34, 37-40, 42-46, & 48-52 stand rejected under 35 U.S.C. 103(a) as being unpatentable over PATEL et al and LILLEY et al WO 01/35925 in view of ALFORD 3737825 or JANS et al 5824336

PATEL provides the coated instant particles, inclusive of coating with benzepril (page 7, line 14), AS ONE OF A DEFINITIVE NUMBER OF ACTIVES, ADMINISTERED TO AN ANIMAL (LINE 16, PAGE 6), over POWDERS, (p.51) of sugar or lactose or starch of 30-35 mesh size (page 51, line 29; page 52, top and Example 1). This is followed by an enteric polymer protective coating of acrylic/methacrylic (Eudragit; Example 6). The particular polymer can be chosen for dissolution at low, or, for sustained release, high, pH. Final dosage forms include pellets and tablets, but are not further described. The coating is of acrylic acid and methacrylic acid polymers and co-polymers. They can be prepared in organic solvents and dissolve at pH of the stomach acid (page 62, lines 11-19).

LILLEY also provides coated actives for animal oral delivery in feed, as very small (.15-.5 mm) particles (p. 7, lines 4-7, claim 4). Example 3 shows solution and coating of a bad tasting animal drug, followed by polymeric coating. Products are tablets (claim 3-6). ALFORD shows how the coated particles, as of the instant shown by PATEL, can be mixed with an animal feed substrate and pelleted (column 2, line 26) or tableted (line 65+) with dical, corn starch.

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JANS also mixes actives with feed substrates to form tablets (column 3). The feed substrate Brewers yeast, mixed with actives and additives (column 2, lines 21, 22).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize a protected feed additive to use one of PATEL and LILLEY modified with the acrylic type coatings of PATEL and with ALFORD or JANS additives in order to provide animal acceptance and include desired nutrients and drugs. The selection of each ingredient or administration method is a result effective parameter chosen to obtain the desired effects. It would be obvious to vary the nature of each ingredient to optimize the effects desired.

There is no unobvious and/or unexpected results obtained since the prior art is well aware of the use of amine compounds for enhancement and the use of ingredients for the functionality for which they are known to be used is not a basis for patentability. Applicant has not provided any objective evidence of criticality, nonobvious or unexpected results that the administration of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed. PATEL shows how to provide coated particles of actives for animal consumption. Selection of the instant would be within the purview of the animal practitioner, given a limited number of actives are shown (see KSR V TELEFLEX @ 82 USPQ 2d @ 1385)

It would be obvious to formulate as pellet or tablet, as PATEL so directs. Inclusion of feed components in forming the tablet would be an obvious basis for improving attractiveness and palatability to insure animal compliance. Such examples of feed components with actives are shown by ALFORD and JANE. Given these guidelines, the formulator would know an active inclusive of benazepril could be prepared with expectation of animal ingestion.

***Response to Arguments***

Applicant's arguments filed 11/02/09 have been fully considered but they are not persuasive. Applicant states coating is benzapril alone, it is not. It is "consisting essentially" guise, and so can include other non-deleterious components (surfactants). Neither is the sieve size unimportant-that is the standard size of PATEL's carrier (sugar) particles, and includes the instant size.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT A. WAX can be reached on 571-272-0623. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NEIL LEVY/  
Primary Examiner, Art Unit 1615  
1/21/2010